RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK ENDOSCOPIC CLIPPING DEVICE

K023903

Pg 1 of 2

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 2 0 2003

Submitted By:
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Device Description:
The Wilson-Cook Endoscopic Clipping Device is comprised of an introducer with a locking handle and one (1) pre-loaded clip. The introducer is used to deploy the clip and is not left in the patient. The clip is left in the patient to accomplish hemostasis.

Trade Name: Wilson-Cook Endoscopic Clipping Device

Common/Usual Name: Endoscopic Clipping Device

Classification Name/Code: Clip, Hemostatic / MCH

Classification: FDA has classified similar devices as Class II. This device falls within the purview of the Gastroenterology and Urology Device Panel.

Performance Standards: To the best of our knowledge, performance standards for this device do not exist.

Intended Use: Used for endoscopic clip placement within the gastrointestinal tract for the purpose of endoscopic marking, hemostasis for mucosal/submucosal defects less than 3 cm in the upper GI tract, bleeding ulcers, arteries less than 2 mm, and polyps less than 1.5 cm in diameter in the GI tract. This device is not intended for the repair of GI tract lumenal perforations.

Predicate Device:

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
Olympus Endoscopic Clipping Device	Olympus America, Inc	K990687

Substantial Equivalence:
The Wilson-Cook Endoscopic Clipping Device is substantially equivalent to the referenced predicate device with respect to design, materials of construction and intended use.

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK ENDOSCOPIC CLIPPING DEVICE

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

DEVICE CHARACTERISTIC	Wilson-Cook Endoscopic Clipping Device [Subject of 510(K)]	Olympus Endoscopic Clipping Device
510(k) Number	Not assigned	K990687
Intended Use	Used for endoscopic clip placement within the gastrointestinal tract for the purpose of endoscopic marking, hemostasis for mucosal/ submucosal defects less than 3 cm in the upper GI tract, bleeding ulcers, arteries less than 2 mm, and polyps less than 1.5 cm in diameter in the GI tract. This device is not intended for the repair of GI tract lumenal perforations.	Used for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of endoscopic marking, hemostasis in the upper GI tract for mucosal/submucosal defects < 3 cm, bleeding ulcers and arteries < 2 mm, polyps < 1.5 cm in diameter, and anchoring to affix jejunal feeding tubes to the wall of the small bowel. This device is not intended for the repair of GI tract.
Sterility	Sterile, Disposable	Sterile, Disposable

Discussion of Tests and Test Results:

The Wilson-Cook Endoscopic Clipping Device underwent simulated use testing and biocompatibility testing. Test results provide reasonable assurance the device will perform in accordance with its intended use.

Conclusions Drawn from Tests:

Being similar to predicate devices with respect to intended use and technology, and having test results that indicate the device will perform in accordance with its intended use, the Wilson-Cook Endoscopic Clipping Device meets the requirements for 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2003

Ms. Margaret J. Posner
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K023903
Trade/Device Name: Wilson-Cook Endoscopic Clipping Device
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: 78 MND
Dated: November 16, 2002
Received: November 22, 2002

Dear Ms. Posner

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023903

Device Name: Wilson-Cook Endoscopic Clipping Device

Indications for Use:

Used for endoscopic clip placement within the gastrointestinal tract for the purpose of endoscopic marking, hemostasis for mucosal/ submucosal defects less than 3 cm in the upper GI tract, bleeding ulcers, arteries less than 2 mm, and polyps less than 1.5 cm in diameter in the GI tract. This device is not intended for the repair of GI tract lumenal perforations.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter _____ (Optional Format 1-2-96

David A. Syracuse

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023903